K023014

MAR 11 2003

501(k) Summary

Submitted by	Address	Telephone	Contact Person
Orthovita, Inc.	45 Great Valley Parkway Malvern, PA 19355	(610) 640-1775	Andreina Ide Sr. Director, Regulatory Affairs

September 2002	Subject Device	Predicate Device
Trade Name	Imbibe™ Bone Marrow Aspiration Syringe	Imbibe™ Bone Marrow Aspiration Syringe, K011087
Common Name	Bone Graft Delivery Syringe	Bone Graft Delivery Syringe
Classification Name	Piston Syringe	Piston Syringe

Device Description:

The syringe consists of a calibrated hollow barrel and a movable plunger. At the distal end of the syringe there is a male connector (nozzle) for fitting the female connector (hub) of a single lumen aspiration needle. A luer-lock nozzle makes a stable connection between the syringe and needle. (*Please note that the needle is not the subject of this 510(k).*) A threaded screw cap (containing the luer-lock nozzle) at the distal end of the syringe can be removed to allow the user to fill the syringe with his or her choice of bone void filler. Alternatively, the plunger can be removed to add bone void filler from the proximal end of the syringe.

After filling the syringe with bone void filler, the user attaches a needle by way of the luer-lock, and percutaneously aspirates blood or marrow into the barrel of the syringe. Once the desired volume of blood or marrow has been collected, the threaded screw cap is removed and the contents of the syringe are delivered to the surgical site.

Intended Use:

The IMBIBE Bone Marrow Aspiration Syringe is intended for use as a piston syringe for the aspiration of bone marrow, autologous blood, plasma or other blood components. Prior to use, the syringe can be filled with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). This syringe provides the surgeon with a convenient way to mix autologous blood or bone marrow with bone void filler (bone graft) and deliver the material to the orthopaedic surgical site.

COMPARISON TO PREDICATE (Original) SYRINGE		
	Predicate Syringe, K011087	**Modified Syringe**
Syringe Type	Piston Syringe	Piston Syringe
Intended Use	To collect blood components/bone marrow for mixing with bone graft and subsequent delivery to the surgical site.	Identical
Principle of Operation	▪ Syringe used to collect blood, marrow ▪ Removable cap allows syringe to be filled with graft material ▪ Syringe provides for mixing of blood, marrow with graft material ▪ Removable screw cap allows for delivery of blood, marrow filled graft to surgical site	Identical
Barrel Length	2.93 inches	2.93, 3.25, 3.47, and 5.23 inches for the 10, 20, 30 and 60cc syringes, respectively
Barrel Diameter	0.728 inches, OD	0.728, 0.898, 1.038, and 1.186 inches OD for the 10, 20, 30 and 60cc syringes respectively
Tip Type	Gasket	Gasket
Volume	10cc	10cc, 20cc, 30cc, 60cc
Nozzle Type	Luer-lock	Luer-lock
Barrel Markings	Graduated scale	Graduated scale
Lubricant Composition	Silicone	Silicone
Lubricant amt/cm^2	100mg ± 5mg	25 mg maximum for all sizes
Barrel Transparency	Transparent, no radiopacifiers	Transparent, no radiopacifiers
Reuse	Single use only	Single use only
Biocompatibility	Established	Established by way of predicate device, K011087
Materials	Polycarbonate, ABS, Silicone	Polycarbonate, ABS, Silicone, PVC
Sterility	gamma radiation	gamma radiation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2003

Orthovita, Inc.
Andreina Ide
Senior Director, Regulatory Affairs
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K023074
Trade/Device Name: IMBIBE™ Bone Marrow Aspiration Syringe
Regulation Number: 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 10, 2003
Received: February 11, 2003

Dear Ms. Ide:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K023074

DEVICE NAME: Imbibe™ Bone Marrow Aspiration Syringe

INDICATIONS FOR USE:

The Imbibe Bone Marrow Aspiration Syringe is intended for use as a piston syringe for the aspiration of bone marrow, autologous blood, plasma or other blood components. Prior to use, the syringe can be filled with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). This syringe provides the surgeon with a convenient way to mix autologous blood or bone marrow with bone void filler (bone graft) and deliver the material to the orthopaedic surgical site.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter-Use**____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023074